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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

BARBARA HEINRICH and GREGORY
HEINRICH,

Plaintiffs

v.

ETHICON, INC., et al.,

Defendants

Case No.: 2:20-cv-00166-APG-VCF

**Order Denying Plaintiff's Motions to
Exclude Dr. Flynn's Opinions**

[ECF Nos. 51/52, 72-7/72-8]

Plaintiff Barbara Heinrich alleges that she suffered injuries after being implanted with the TVT-SECUR (TVT-S) product, which was designed and manufactured by defendants Johnson & Johnson and Ethicon, Inc. ECF No. 4. Heinrich filed two motions to exclude the general and case-specific causation opinions of the defendants' expert, Dr. Brian Flynn. ECF Nos. 51/52 (specific); 72-7/72-8 (general). The defendants opposed. ECF Nos. 56 (specific); 72-9 (general). The parties recently filed supplemental briefs identifying the remaining issues as (1) the reliability of Dr. Flynn's general causation opinions about TVT-S's safety and efficacy, (2) Dr. Flynn's ability to base his case-specific opinions on his personal experience, and (3) Dr. Flynn's opinions on laser versus mechanical cut mesh. ECF Nos. 118; 121. I held a *Daubert*¹ hearing on April 30, 2021. ECF No. 139. I deny Heinrich's motions.

Federal Rule of Evidence 702 governs the admissibility of Dr. Flynn's opinions. Under Rule 702, a witness "who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

¹ *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

- 1 (a) the expert’s scientific, technical, or other specialized knowledge will
2 help the trier of fact to understand the evidence or to determine a fact in
3 issue;
4 (b) the testimony is based on sufficient facts or data;
5 (c) the testimony is the product of reliable principles and methods; and
6 (d) the expert has reliably applied the principles and methods to the facts
7 of the case.

8 To be admissible, expert testimony thus must be both relevant and reliable.² “Expert opinion
9 testimony is relevant if the knowledge underlying it has a valid connection to the pertinent
10 inquiry. And it is reliable if the knowledge underlying it has a reliable basis in the knowledge
11 and experience of the relevant discipline.” *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010),
12 *as amended* (Apr. 27, 2010). Medical expert testimony should be admitted “if physicians would
13 accept it as useful and reliable, but it need not be conclusive because medical knowledge is often
14 uncertain.” *Id.* (quotation omitted). Where there is a sufficient foundation for the testimony, it is
15 up to the jury to evaluate the expert’s credibility. *Id.* at 565-66.

16 Rule 702’s inquiry is “flexible,” and should be applied in favor of admitting the evidence.
17 *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1232 (9th Cir. 2017) (quotation omitted).
18 “Shaky but admissible evidence is to be attacked by cross examination, contrary evidence, and
19 attention to the burden of proof, not exclusion.” *Primiano*, 598 F.3d at 564.

20 **A. General Causation Opinions on Safety and Efficacy**

21 One way to show that an expert’s testimony is based on scientifically valid principles “is
22 by proof that the research and analysis supporting the proffered conclusions have been subjected
23 to normal scientific scrutiny through peer review and publication.” *Wendell*, 858 F.3d at 1235
(quotation omitted). However, an expert’s opinion based on a review of medical literature “may
be unreliable if he fails to account for contrary scientific literature and instead selectively

² Heinrich does not dispute that Dr. Flynn’s opinions are relevant.

1 [chooses] his support from the scientific landscape.” *Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-
2 05762, 2014 WL 4851989, at *11 (S.D. W. Va. Sept. 29, 2014) (quotation omitted, gathering
3 cases).

4 Judge Goodwin stated that the foundation of Dr. Flynn’s general opinions regarding
5 safety and efficacy is “shaky” to the extent Dr. Flynn relies on medical literature because he
6 “focused only on medical literature that supported his position, ignoring relevant, contrary
7 medical literature while not explaining his reason for doing so.” ECF No. 81-5 at 10. In
8 Heinrich’s original motion and supplemental brief, she identified only one contrary medical
9 review related to TVT-S that Dr. Flynn did not consider, a Cochrane review entitled Single
10 Incision Sling Operations for Urinary Incontinence in Women (“Single Incision Review”) by
11 Nambiar, et al. However, Dr. Flynn had reviewed it, it is included in his reliance list, and he
12 testified that he reviewed all materials on his reliance list. He also explained that although he did
13 not mention the report by name, he referenced it generally with other studies. Flynn identified
14 the studies he relied on, explained why he concluded that those studies better reflect the TVT-S,
15 and explained why the Single Incision Review did not change his opinions on the TVT-S’s
16 safety and efficacy. Flynn’s review of the relevant literature was extensive, and his testimony
17 based on the medical literature is admissible. Any flaws in Flynn’s decision to discount the
18 Single Incision Review can be explored through cross examination and will be a matter for the
19 jury to resolve. Consequently, I deny Heinrich’s motion to exclude Flynn’s general causation
20 opinions based on his review of the medical literature.

21 **B. Personal Experience**

22 Experience alone may constitute a sufficiently reliable basis for expert testimony. *Kumho*
23 *Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 156 (1999); Fed. R. Evid. 702 advisory committee’s

1 note to 2000 amendment (stating that “the text of Rule 702 expressly contemplates that an expert
2 may be qualified on the basis of experience”). But if “the witness is relying solely or primarily
3 on experience, then the witness must explain how that experience leads to the conclusion
4 reached, why that experience is a sufficient basis for the opinion, and how that experience is
5 reliably applied to the facts.” Fed. R. Evid. 702 advisory committee’s note to 2000 amendment.
6 “Because medical expert opinion testimony is based on specialized as distinguished from
7 scientific knowledge, the *Daubert* factors are not intended to be exhaustive or unduly
8 restrictive.” *United States v. Sandoval-Mendoza*, 472 F.3d 645, 655 (9th Cir. 2006) (quotation
9 omitted). Medical expert testimony should be admitted “if physicians would accept it as useful
10 and reliable.” *Id.*

11 A medical expert need not be able to testify “as to exact statistics about his patients . . . to
12 opine as to the large-scale safety and efficacy” of a medical device. *Winebarger v. Bos. Sci.*
13 *Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *34 (S.D. W. Va. Apr. 24, 2015) (emphasis
14 omitted). Rather, such an opinion may be sufficiently reliable if it is based on the expert’s
15 observations in his own clinical practice that is “on par with the findings” in medical literature
16 the expert cites. *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014), *as*
17 *amended* (Oct. 29, 2014) (quotation omitted).

18 Flynn is qualified to render the opinions he offers. He is a urologist who has performed
19 over 1,100 stress urinary incontinence (SUI) procedures. He has used mesh in over 800 of those
20 cases, including 500 using some form of TVT product. *Id.* He used TVT-S starting in 2007, and
21 it was the most common device he used from 2008-2010, implanting it approximately 175 times.
22 *Id.* at 129. In addition to his clinical practice, he teaches and has published scientific articles in
23 peer review journals on reconstructive urologic surgery. *Id.*

1 Heinrich contends that Flynn nevertheless should be precluded from basing his opinions
2 on his own experience because he refused to provide a spreadsheet that he maintains on the
3 procedures he has performed, he has no experience with long term complications, and he ignores
4 poor results in his own cases. To the extent Heinrich contends Flynn should not be allowed to
5 testify because he did not disclose the spreadsheet, there is no indication she moved to compel its
6 production. Flynn testified that he referred to the spreadsheet to identify the number of
7 procedures he performed overall and with certain products. Heinrich does not dispute Flynn has
8 conducted hundreds of procedures to treat SUI using a variety of products, including the TVT-S.
9 His reference to the spreadsheet to confirm those numbers does not make his testimony
10 inadmissible, particularly because he need not refer to exact statistics to form his opinion on the
11 TVT-S's large scale safety and efficacy.

12 Flynn testified at the hearing about his experience with long term complications related to
13 patients who are referred to him for explant procedures as well as his own implant patients. He
14 also explained why he thought his own patients would, by and large, return to him if they
15 experienced complications. And he discussed his experience relating to a study he published, as
16 well as his comments at a professional meeting, which according to Heinrich shows he ignores
17 poor results in his own patients. Heinrich's critiques are matters for cross examination and go to
18 the weight of Flynn's testimony, not its admissibility. I therefore deny Heinrich's motion to
19 exclude Flynn's case-specific opinions based on his experience.

20 **C. Laser v. Mechanical Cut Mesh**

21 Flynn opined in his general causation report that there is no difference between laser and
22 mechanical cut mesh. Flynn based this opinion on studies before and after the introduction of
23 laser cut mesh that showed no difference in terms of safety, his own experience with both types

1 of cutting methods, and his finding that nothing in the medical literature has noted a difference
2 based on the cut. In his addendum to his report, Flynn identified a more recently published study
3 finding no clinically significant difference between the two cutting methods. Flynn has
4 explained the bases of his opinion, and it is grounded in the medical literature and his own
5 experience. The fact that he is not a materials scientist does not preclude him from opining on
6 whether the two cuts have clinically significant differences. I therefore deny this portion of
7 Heinrich's motion to exclude Flynn's general causation opinion regarding the cutting methods.

8 **D. Conclusion**

9 I THEREFORE ORDER that the plaintiffs' motions to exclude certain of Dr. Flynn's
10 opinions and testimony (**ECF Nos. 51/52, 72-7/72-8**) are **DENIED**.

11 DATED this 10th day of May, 2021.

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14 ANDREW P. GORDON
15 UNITED STATES DISTRICT JUDGE
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